

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas
Le groupe de travail technique de l'ALENA sur les pesticides

Biopesticides Registration Improvement Course

**ECOTOXICOLOGICAL INFORMATION REQUIREMENTS
FOR PESTICIDE REGISTRATION
(MICROBIAL, BOTANIC AND BIOCHEMICAL PESTICIDES)**

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Environment
Mexico





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DEFINITIONS

Biochemical pesticide

- Natural substance that control pests through no toxics mechanisms. This kind of pesticide include insect sexual pheromones that disrupt the copulation process.

Botanic pesticide

- Substance extracted directly form plants that are fitted out to be use for pests control .

Microbial pesticide

- Product formulated based on microorganisms, such as bacteria, virus, fungi or yeasts, nematodes or protozoa, and used to control pests.



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LEGAL FRAMEWORK (SEMARNAT)

In the case of SEMARNAT, based in the following articles of the General Law of Ecological Equilibrium and Environmental Protection (LGEEPA): 120 fraction V, 134 fraction IV, 135 fraction IV, 143, 144, 150 and 153 fractions I, II, III, IV, V, VII, and VIII, it was allowed to participate in the development and publications of the Regulation in Respect of Registration, Import and Export Authorizations and Certificates for Export of Pesticides, Fertilizers and Toxic and Hazardous Substances (PLAFEST Regulation), published in the Federal Gazette (D.O.F.) on December 28th, 2004.



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LEGAL FRAMEWORK (SEMARNAT)

PLAFEST Regulation

- SEMARNAT has the responsibility to issue a technical opinion regarding the environmental protection, after the analysis and assessment of the technical and ecotoxicological information (3rd article).
- There will only be accepted the studies and methodologies about physicochemical properties, toxicological effects, ecotoxicological effects and environmental fate that are developed according to internationally recognized scientific guidelines (4th article).
- Section fourth: the information about ecotoxicological effects and environmental fate and a copy of the label project de (10th article).



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LEGAL FRAMEWORK (SEMARNAT)

Internal Regulation of the Environment and Natural Resource Ministry, published November 30th, 2006 in the Federal Gazette (D.O.F)

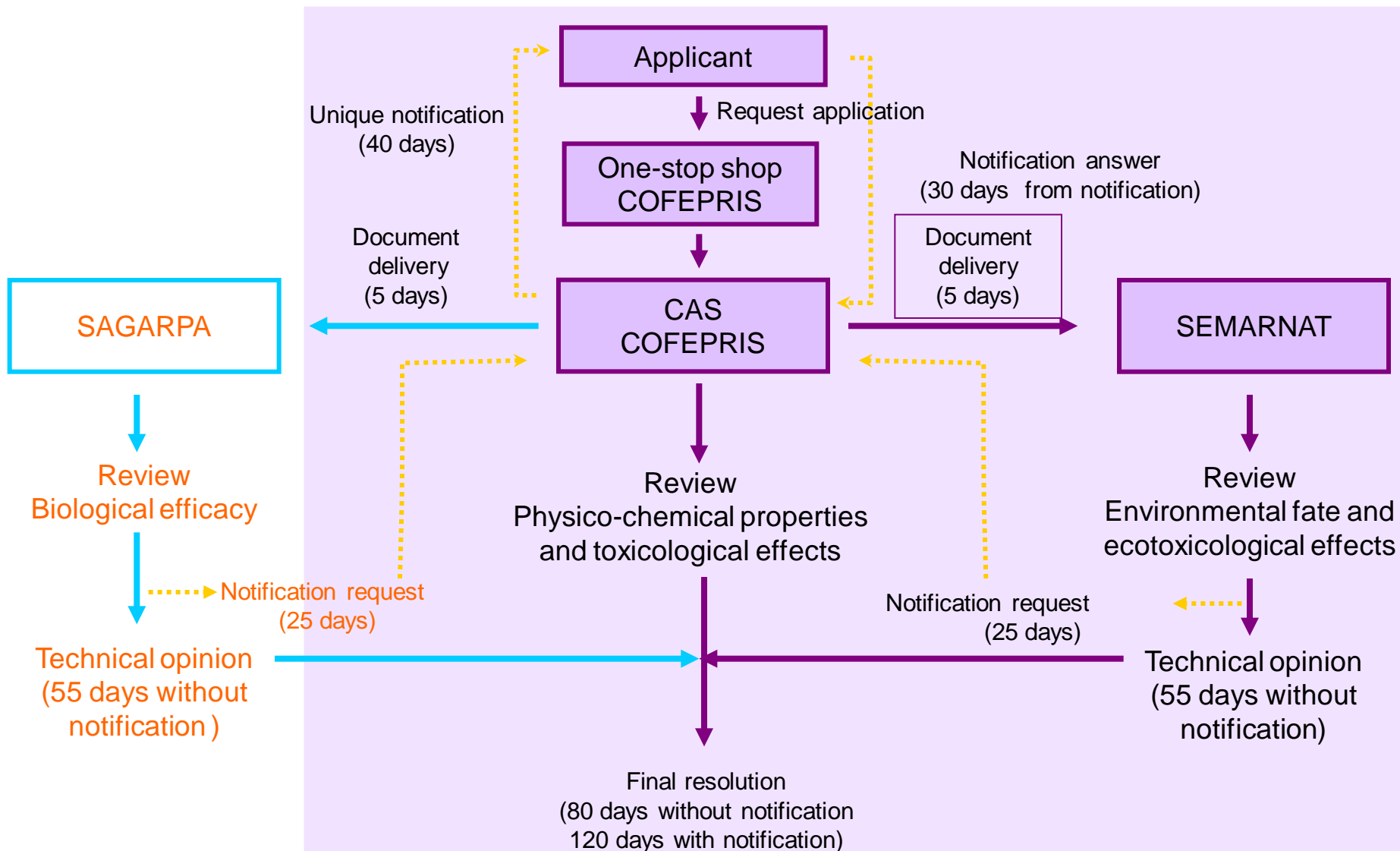
The General Direction of Integrated Management of Risky Materials and Activities has within its attributions (28th article):

Participate in the regulation and authorization of the process, use and registration of pesticides and fertilizers, as well as in their import and export.



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REGISTRATION PROCEDURE (PLAFEST Regulation, 9th article)





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INFORMATION REQUIRED FOR PESTICE REGISTRATION

1. Application official form for pesticide registration (properly completed).
2. Document certifying the legal status of the applicant.
3. Required documentation (PLAFEST Regulation, 11th and 12th articles) according to the type of product to be registered.
4. Receipt of fees payment.
5. Copy of the Operation Notification in the case of pesticide distributors or the sanitary license number in the case of pesticide manufacturers or formulators.



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SUBMIT THE INFORMATION CLASSIFIED ACCORDING TO THE FOLLOWING SECTIONS:

•**First**: application official form for pesticide registration, document certifying the legal status of the applicant and receipt of fees payment.

•**Second**: Information related to product identity and composition, its physical, chemical and biological properties, analytical methods, technical information, quantification and laboratory analysis, manufacture summaries, maximum impurities level, characteristics related to its use.

•**Fifth**: Copy of the information about the characteristics related to its use, number of the biological effectiveness opinion and copy of label project, in the case of agricultural and livestock pesticides.

•**Forth**: Ecotoxicological information and copy of the label project.

•**Third**: Toxicological information, maximum residues level and label project.



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THE APPLICATION REQUEST SHOULD BE SUBMITTED WITH THE FOLLOWING DOCUMENTATION.

National manufactured pesticides that require active ingredients of elements from a provider, original letter form this providers that specify the following:

- ✓ **Commercial name and common name of the product, as well as its percentage composition;**
- ✓ **Name and address of the provider, and**
- ✓ **Name and address of the product buyer, who correspond to the applicant for pesticide registration.**

National manufactured pesticides that do not require active ingredients or elements from a provider, it should be submitted a letter expressing under oath that situation.



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THE APPLICATION REQUEST SHOULD BE SUBMITTED WITH THE FOLLOWING DOCUMENTATION.

In the case of imported pesticides:

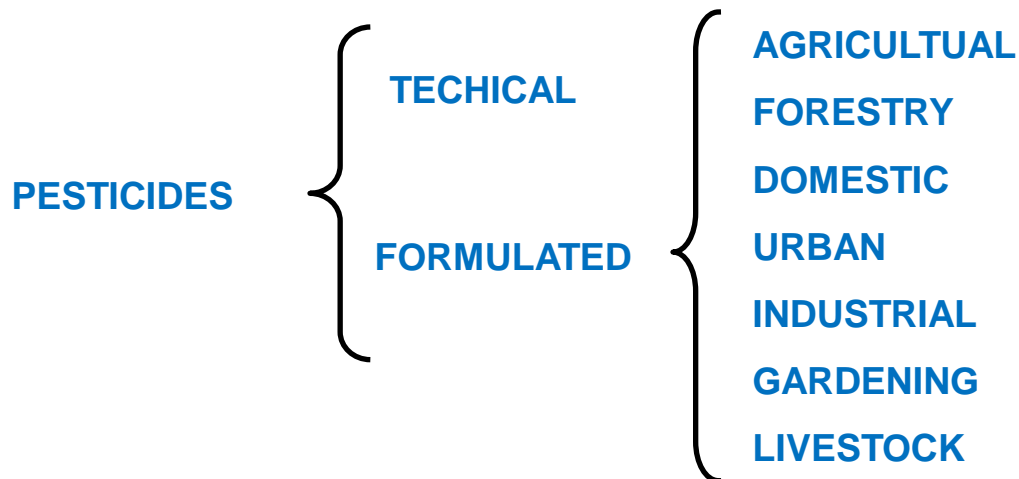
- ✓ Original letter from the provider that specify the following data:
 - Commercial name and common name of the product, as well as its percentage composition;
 - Name and address of the provider,
 - Name and address of the product buyer (applicant for pesticide registration), and
 - Number of the pesticide current registration in the country or countries it comes from, when the active ingredients are imported
 - Current certified registration issued by the competent authority from the country where the product is manufactured.



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INFORMATION ABOUT ECOTOXICOLOGICAL EFFECTS AND ENVIRONMENTAL FATE

Applicants should present the **information and documents** according to the **type of product** they want to registry (12th article), for registration of both national and imported products.





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INFORMATION ABOUT ECOTOXICOLOGICAL EFFECTS AND ENVIRONMENTAL FATE

A technical opinion is issued about:

Ecotoxicological Information

- Pesticide effects on terrestrial plants and animals
- Effects on aquatic plants and animals
- Impact on populations of benefic and pollinator insects

Environmental Fate

- Degradation index and concentration of pesticide residues in soil, plants and water
- Metabolite identity in soil, plants and water
- Lixiviation, mobility, accumulation and persistency in water and soil
- Studies about photodegradation, hydrolysis y chemical adsorption

Label Project

- Legends about the measures for de environmental protection



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STUDIES AND METHODOLOGIES

The studies and methodologies that are accepted are those carried out according to international guidelines, such as:

Guidelines for Assay and Assessment of Chemical Products and GLP guidelines, developed by OECD.

UN Guidelines about Environmental Criteria for Pesticide Registration.

FAO and WHO Manual for Elaboration and Use of Pesticide Specifications.

Analytical Methods developed by the International Council for Pesticide Collaboration.

EPA guidelines and CEE methods (8th transitory article).



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MICROBIAL PESTICIDES

Microbial

Bacteria

Fungi

Virus

Nematodes

Protozoa

ECOTOXICOLOGICAL INFORMATION

- ✓ Studies of pesticide effects on terrestrial plants and animals.



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MICROBIAL PESTICIDES

ECOTOXICOLOGICAL INFORMATION

- ✓ Effects on aquatic plants and animals.
- ✓ Study of the acute mean lethal concentration (LC_{50}) at 96 h of exposure in fish.



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MICROBIAL PESTICIDES

ECOTOXICOLOGICAL INFORMATION

- ✓ Study of the acute mean lethal concentration (LC_{50}) at 48 h of exposure of an animal of plant, which feeds a fish specie conventionally used as an ideal ecological indicator.

Daphnias

Algae



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MICROBIAL PESTICIDES

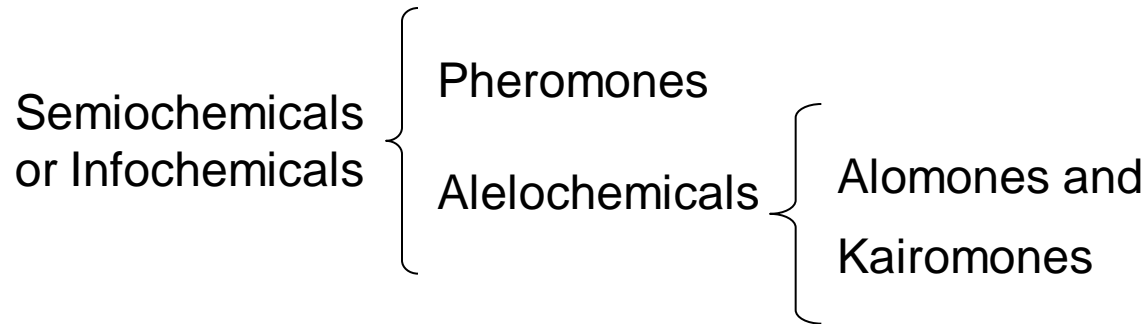
ECOTOXICOLOGICAL INFORMATION

- ✓ Study about the impact on populations of benefic and pollinator insects.
- ✓ Label project – legends about measures for environmental protection.



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BIOCHEMICAL PESTICIDES
(12th article, fraction V).



Requirements:

- **Label project that fulfils the Mexican Official Standards (NOM-232-SSA1-2009).**



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BOTANIC PESTICIDES
(12th articles, fraction VII)

Requirements:

- **Label project that fulfils the Mexican Official Standards (NOM-232-SSA1-2009).**



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MICROBIAL PESTICIDEA BASED IN GENETICALLY MODIFIED ORGANISMS (12th article, fraction VIII)

Ecotoxicological studies

- Percentage of gene transference
- Relative competitiveness between donor races in soil, water and air

- **Label project** that fullfiles the corresponding Mexican Official Standards



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PESTICIDE REGISTRATION AND EQUIVALENT TECHNICAL CHANGES UNDER THE SAME METHOD

MICROBIAL PESTICIDES

Requirements

- Official form for registration request (properly completed).
- Microbial pesticides (**Ecotoxicological information**):
 - Pesticide effects on terrestrial plants and animals.
 - Pesticide effect on aquatic plants and animals.
 - Studies of impacts on populations of benefic and pollinator insects.

➤ **Label project** complying with the provisions of the official Mexican standards that are applicable and, where appropriate, with the general provisions to this effect issued.



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PESTICIDE REGISTRATION AND EQUIVALENT TECHNICAL CHANGES UNDER THE SAME METHOD

Based pesticide genetically modified organisms

REQUIREMENTS:

Ecotoxicological studies with the author's name, laboratory or institution that conducted the investigation.

- Percentage of gene transference
- Relative competitiveness between donor races in soil, water and air

➤ **Label project** that fulfills the corresponding Mexican Official Standards



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REGISTRATION OF PESTICIDE EXCLUSIVELY FOR EXPORTATION

Registration of pesticides exclusively for exportation and that will not be marketed or used in Mexico.

Requirements

- Official form for registration request (properly completed).
- Microbial pesticides (**Ecotoxicological information**):
 - Pesticide effects on terrestrial plants and animals.
 - Pesticide effect on aquatic plants and animals.
 - Studies of impacts on populations of benefic and pollinator insects.



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REGISTRATION OF PESTICIDE EXCLUSIVELY FOR EXPORTATION

Registration of pesticides based on genetically modified organisms

REQUIREMENTS:

- Official form of registration requirement.
 - Ecotoxicological studies with the author's name, laboratory or research institution that performed.
-
- Percentage of gene transference, and
 - Relative competitiveness between donor races in soil, water and air.



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LABEL PROJECT

Under the title of “MEASURES FOR ENVIRONMENTAL PROTECTION”

DURING PRODUCE HANDLING

AVOID CONTAMINATION OF
SOIL, RIVERS, LAKES,
STREAMS, DAMS, CANALS OR
DEPOSITS OF WATER, BY NOT
WASHING OR POURING IN
PESTICIDE RESIDUES OR
PESTICIDE EMPTY
CONTAINERS.

RESIDUE AND EMPTY CONTAINER MANAGEMENT

HANDLE THE PRODUCT
ACCORDING TO THE
PROVISIONS OF THE
GENERAL LAW FOR THE
PREVENTION AND INTEGRAL
MANAGEMENT OF WASTES
AND ITS REGULATION, OR
ACCORDING TO A
MANAGEMENT PLAN FOR
EMPTY CONTAINERS THAT
HAD BEEN REGISTERED TO
SEMARNAT.



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LABEL PROJECT

Under the title of “MEASURES FOR ENVIRONMENTAL PROTECTION”

IN CASE OF LIQUID PRODUCT SPILL

PERSONAL PROTECTION
EQUIPMENT MUST BE USED
AND THE SPILLED
PRODUCT MUST BE
COLLECTED USING AN
ABSORBENT MATERIAL
(FOR EXAMPLE SOIL OR
CLAY), PLACED IN THE
WASTES IN AN HERMETIC
CONTAINER AND TAKE IT TO
THE NEAREST AUTHORIZED
CENTER FOR HAZARDOUS
WASTE COLLECTION.

IN CASE OF ACCIDENTAL RELEASE OF SOLID PRODUCT

PERSONAL PROTECTION
EQUIPMENT MUST BE USED
AND THE PRODUCT THAT IS
STILL USEFUL MUST BE
COLLECTED. THE
REMAINING PRODUCT
MUST BE PICKED UP
PLACED IN AN HERMETIC
CONTAINER AND TAKE IT TO
THE NEAREST AUTHORIZED
CENTER FOR HAZARDOUS
WASTE COLLECTION.



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LABEL PROJECT

ADVERCE EFFECTS ON AQUATIC AND TERRETIAL PLANTS AND ANIMALS (ECOLOGICAL RISKS)

LEGEND	IT WILL BE APPLIED WHEN:
ECOTOXICOLOGICAL CATEGORY THIS PRODUCT IS HIGHLY TOXIC POR WARM-BLOODED TERRESTRIAL ANIMALS (MAMMALS Y BIRDS).	<ul style="list-style-type: none"> - Acute oral mean lethal dose (LD₅₀) in mammals is 10 to 50 mg/kg of body weight. - Acute oral mean lethal dose (LD₅₀) in birds 10 to 50 mg/kg. - Acute dietary mean lethal concentration (LC₅₀) in birds is 50 to 500 ppm in food.
THOS PRODUCT IS HIGHLY TOXICO FOR BEES. DO NOT APPPLY IT WHEN CROPS OR WEEDS ARE FLOWERING AND THE BEES ARE SUCKING.	<ul style="list-style-type: none"> - Mean lethal dose (LD₅₀) is < 2.0 mg/bee.



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EXCEPTION TO PLAFEST REGULATION

When reasonable technical and scientific arguments exists to consider that the **administrative or ecotoxicological documents are not necessary or applicable for pesticide registration**, the applicant should present in his request a reasoned scientific analysis and the corresponding official documentation.

• (5th article)



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EXCEPTION TO PLAFEST REGULATION

Applicant is not required to present the ecotoxicological information when he has a registration for technical pesticide or the same active ingredient and the product to be registered is provided by the same company or person of the previous registration. In this case, the registry number that he possesses should be presented.

- (Final paragraph of fraction III, 12th article)



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EXCEPTION TO PLAFEST REGULATION

When the applicant does not have the toxicological and **ecotoxicological information** required, he should present a **letter issued by the provider of the product** that allows him the access to this information used to previously register the same product.

- (13th article)

Which must be the same as the person sought to be registered.



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“Thanks for your attention”

**DIRECCIÓN GENERAL DE GESTIÓN INTEGRAL DE
MATERIALES Y ACTIVIDADES RIESGOSAS.**

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